

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

THE COUNTY OF SUMMIT, OHIO, Plaintiff, v. EXPRESS SCRIPTS, INC., EXPRESS SCRIPTS PHARMACY, INC., EXPRESS SCRIPTS HOLDING COMPANY, MEDCO HEALTH SOLUTIONS, INC., MERCK-MEDCO, UNITEDHEALTH GROUP, INC., OPTUM, INC., OPTUMRx, INC. Defendants.	MDL No. 2804 Case No.: Judge Dan Aaron Polster COMPLAINT IN A CIVIL ACTION JURY TRIAL DEMANDED
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The Plaintiff, the County of Summit, Ohio, brings this action against Defendants Express Scripts, Inc., Express Scripts Pharmacy, Inc., Express Scripts Holding Company, Medco Health Solutions, Inc., Merck-Medco, UnitedHealth Group, Inc., Optum, Inc., and OptumRx, Inc. in order to abate the public nuisance caused in part by Defendants' unreasonable acts and omissions in facilitating the use of opioids by favoring, and failing to restrict, the use of opioid in their formularies and in collaborating with opioid manufacturers to deceptively and dangerously promote and to fail to disclose the risk of opioids, as well as their failures to maintain effective controls to prevent diversion in their own dispensing of opioids, and to monitor their own claims data to prevent suspicious or inappropriate prescriptions of dangerously lethal opioids from reaching the community. In support of its claims, the Plaintiff states as follows:

INTRODUCTION

1. This case arises from the worst man-made epidemic in modern medical history – the over-prescription, misuse, and abuse of opioids.

2. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The CDC's National Center for Health Statistics provides provisional data on drug overdose deaths. According to the data, there were an estimated 107,622 drug overdose deaths in the United States during 2021. That is nearly a 15% increase from the estimated deaths in 2020.

3. From 1999 through 2016, more than 350,000 people died from an overdose involving any opioids. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

4. Many of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Individuals who used prescription opioids more recently have turned to or been exposed to fentanyl, with even more lethal effects.

5. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

6. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control and Prevention, “I don’t think we’ve ever seen anything like this. Certainly not in modern times.” On October 27, 2017, then-President Trump declared the opioid epidemic a public health emergency. Just weeks ago, on December 22, 2022, Health and Human Services Secretary Xavier Becerra renewed the determination that “a opioid public health emergency exists nationwide.

7. From 2015 to 2021, according to the state OARRS (Ohio Automated Rx Reporting System) data, Summit County – with a population of 540,000 residents—averaged 21.5 million doses of opioids dispensed per year, with a high of 32.7 million in 2015.

8. Ohio is at the epicenter of the opioid epidemic. “Opioid addiction, abuse and overdose deaths have become the most pressing public health issue facing Ohio.” In 2017, Ohio “[led] the country in drug overdose deaths per capita, a rate that continue[d] to rise, overwhelming families, communities, and local governments across the state.” Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and a half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids.

9. In 2020, an average of 14 Ohioans died every day from fatal drug overdoses, with a total of 5,017 lives lost to overdose that year. Provisional data from the CDC showed the crisis continuing with 5,358 Ohio overdose deaths recorded in the 12 months ending July 2021. Most of the overdose fatalities in Ohio involved opioids. Due to incomplete reporting, these grim numbers likely understate the number of lives lost.

10. Tragically, “Ohio’s death rate has grown faster than the national rate.” From 2000 to 2012, the State experienced a more than 366% increase in drug overdose deaths, a startling

statistic driven largely by overdoses from prescription drugs. Measured from 2000 to 2015, the numbers are even more staggering: the rate of unintentional drug poisonings in Ohio jumped 642%, with the increase driven largely by opioid-related overdoses. In 2015, there were 3,050 Ohio overdose deaths, up 20.5% from 2,531 Ohio overdose deaths in 2014. Eighty-five percent of these overdoses involved opioids.

11. Summit County is no exception to this deadly trend.

12. In Summit County, the epidemic, as County Executive Ilene Shapiro has noted “does not appear to be slowing down, and the numbers are staggering.” More people died in Summit County from drug overdoses in 2015 and 2016 alone than the entire decade of 2000 to 2009. Altogether, 1,053 Summit County residents died from drug overdoses between 2012 and mid-August 2017. Between 2015 and 2021, Summit County suffered 1,449 fatal overdoses, with opiates involved in 1,236 of those deaths.

13. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Further, overdose deaths are not the only consequence. In 2022 alone, Summit County Public Health reported 1,098 overdoses treated in emergency departments; many others have been revived by EMS or community members trained to administer Narcan – an antidote to overdose.

14. The damage inflicted cuts across ages and generations. Many who have succumbed to overdoses have overdosed more than once. Those who survive are often not alone at the time. Family members, including young children, have watched their loved ones lose consciousness or die. Young children, including toddlers, also have been the direct victims of overdoses themselves after coming into contact with opiates.

15. Children are being displaced from their homes and raised by relatives or placed in the County's care due to parents' addiction. Others lose the chance to go home. Unable to be discharged from the hospital with their mothers, babies born addicted to opioids due to prenatal exposure are being placed in the care of the County or local citizens or non-profits who do their best to comfort them through the pain of withdrawal.

16. The opioid crisis was partially fueled and sustained by those involved in the supply chain of opioids: manufacturers, distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs"), including Express Scripts and OptumRx ("Defendants"). Whether by colluding with manufacturers to make opioids more available as a form of pain treatment or by ignoring the mounting evidence of addiction and misuse in their own claims data, PBMs' role in creating and sustaining the opioid epidemic is largely hidden from public scrutiny but nevertheless facilitated the reckless promotion of opioids by manufacturers, the oversupply of opioid shipments by distributors, and the irresponsible dispensing of prescription opioids by numerous pharmacies.

17. PBMs like Defendants Express Scripts and OptumRx are administrators hired by third-party payers (*e.g.*, government entities, insurers, employers) to design and administer prescription drug programs, and are paid for their services by the third-party payer.

18. PBMs are supposed to work for their clients to reduce prescription drug costs. Yet, over time, PBMs have developed a business model that does the opposite, and in doing so, they have adopted business practices designed to increase the utilization of opioids and, in turn, maximize their own profits.

19. PBMs have the power to control drug utilization and access and receive significant payments from manufacturers (*e.g.*, drug rebates) in exchange for services such as formulary management, which dictate what opioids enter the marketplace and with what restrictions.

20. PBMs have contributed substantially to the opioid crisis by colluding with manufacturers to place opioid drugs on their formularies with preferred status and declining to impose limits on their approval for use in exchange for manufacturer rebate payments and fees. As a result, far greater quantities of prescription opioids entered the market than they knew could be necessary for legitimate, safe, or appropriate medical uses.

21. Additionally, because PBMs have access to claims data for all drug prescriptions written for individuals who receive insurance from an insurer with whom the PBM has contracted, PBMs have a unique insight into prescribing habits at both the patient and prescriber levels, as well as data on prescribing and use of opioids in the aggregate. At the individual level, a PBM could monitor its data to identify conduct commonly associated with opioid misuse, addiction, and diversion, such as early refills of opioid prescriptions, multiple prescriptions for one individual or for dangerously high volumes or dosages of opioids or “doctor shopping,” the practice by which individuals receive multiple opioid prescriptions from unknowing prescribers. On the prescriber level, PBMs could identify problematic prescribers who were prescribing unreasonably high volumes of opioids to unreasonably high numbers of patients, co-prescribing opioids with drugs commonly abused with them, such as benzodiazepines, prescribing opioids outside the regular scope of their practice, or who wrote prescriptions for the same dose and duration to all of their patients – all classic signs of “pill mills.” PBMs can also determine the aggregate volume of opioids being used in a geographic area, as well as the diagnosis, duration, and dosages of opioids being used. PBMs such as Express Scripts and OptumRx had access to all of this data well before Ohio and other states established their Prescription Drug Monitoring Programs in order to perform these analyses and stem the tide of the opioid crisis.

22. Since 2014, payments to PBMs by manufacturers as rebates or fees to ensure the formulary placement of their drugs have risen by 16% per annum, and now constitute 40% or more of branded prescription drug costs.

23. Ohio, in general, and Summit County, in particular, are not immune to this conduct. Ohio was among 11 states that began investigating PBMs in 2018. Its investigation—which was not specific to opioids—uncovered concerning PBM conduct that unreasonably inflated prices the State paid for Medicaid prescription drug claims.

24. Express Scripts served as a PBM for residents in Ohio, generally, and in Summit County, specifically, during the relevant time period. On information and belief, Express Scripts is the largest PBM operating in the State of Ohio. One recent study estimates that Express Scripts possesses a 38% market share in Ohio, meaning that Express Scripts handled—and had access to—opioid prescriptions written for more than 1 out of every 3 Ohio residents with prescription drug insurance coverage.

25. Express Scripts provided its services to Summit County residents, as well. In addition to its role as PBM for large Ohio insurers of private sector individuals, including Medical Mutual of Ohio, Express Scripts served as the PBM for County of Summit employees and others who received health insurance directly from the County beginning in 2013.

26. In this role, Express Scripts was contracted by Medical Mutual to be the PBM and provide the benefit to the insurance company.

27. OptumRx served as a PBM for residents in Ohio and Summit County as well, including but not limited to serving as a PBM for the Ohio Bureau of Workers Compensation and other State employee medical benefit plans.

28. Given PBMs' dominant position in the market and level of expertise, PBMs' clients typically accept the offered baseline national formularies with little to no modification. Indeed, customers hire PBMs for their specialized knowledge in constructing and managing prescription drug formularies. In addition, there are often significant financial penalties for deviating from standard formularies, which PBMs rely on to ensure that they can deliver drug sales to their drug manufacturer-partners. Thus, the PBMs' national formularies control what opioids enter the marketplace and with what restrictions. This is precisely the reason that PBM Defendants boast they are uniquely situated to address the opioid crisis.

29. PBMs tout their substantial influence over nationwide drug utilization as one of their strongest selling points to their customers. PBMs are not bystanders in the opioid crisis; they helped fuel the fire.

30. As described *infra*, by unreasonably colluding with opioid manufacturers and by knowingly ignoring their own data that essentially chronicled the opioid epidemic in real time, Express Scripts and OptumRx have placed profits over safety and engaged in unreasonable conduct that substantially contributed to the opioid epidemic.

31. Defendants' conduct has had a severe and far-reaching public health consequence, the costs of which are borne by Plaintiff and other governmental entities.

32. Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained by this public health crisis.

33. Plaintiff brings this suit to help address the devastating march of this epidemic and to hold Defendants responsible for the crisis they helped cause.

JURISDICTION AND VENUE

34. This Court has jurisdiction over the subject matter of this case pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000 and, as explained below, the Plaintiff is of a different citizenship (Ohio) than Defendants (Delaware, California).

35. This Court has personal jurisdiction over the Defendants under R.C. 2307.382 because the causes of action alleged in this Complaint arise out of the Defendants transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or derive substantial revenue from goods used or consumed or services rendered in this state. The Defendants have purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

36. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in the Northern District of Ohio. Venue is also proper under 18 U.S.C. § 1965(a) because the Defendants, are found, have agents, or transact their affairs in this district.

PARTIES

37. Plaintiff, the County of Summit, Ohio (“the County”) is a charter county organized under the laws of the State of Ohio and its Charter and is the fourth most populous county in Ohio. The County has its seat of government at 175 S. Main Street, Akron, Ohio 44308. The County provides many services for its residents, including public assistance, law enforcement services, criminal justice services, and services for families and children. The County brings this action by and through its County Executive Ilene Shapiro and County Prosecutor Sherri Bevan Walsh.

38. This action and the undersigned counsel have been duly authorized by the prosecuting authority and the Summit County Court of Common Pleas.

39. Defendant Express Scripts, Inc. is a Delaware corporation registered to do business in Ohio with its principal place of business in St. Louis, Missouri. During the relevant time, Express Scripts, Inc. provided pharmacy benefit management services nationwide, including in Summit County, Ohio.

40. Defendant Express Scripts Pharmacy, Inc. is a Delaware corporation registered to do business in Ohio with its principal place of business in St. Louis, Missouri. During the relevant time, Express Scripts Pharmacy was registered in Ohio as a mail order pharmacy that dispensed prescriptions nationwide, including in Summit County, Ohio.

41. Express Scripts, Inc. acquired Defendant Medco Health Solutions Inc. in 2012 in a \$29.1 billion deal. As a result of the merger, Defendant Express Scripts Holding Company (“ESHC”) was formed and became the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers. Defendant Express Scripts Holding Company is a Delaware corporation with its principal place of business in St. Louis Missouri.

42. Defendant Merck-Medco was established in mid-2002 by Merck & Co as its pharmacy benefits management subsidiary, as a separate, publicly traded company.

43. According to its SEC filing, in August 2003, Merck & Co. approved a spin-off, called Medco Health Solutions, Inc., a “wholly owned subsidiary of Merck that provides pharmacy benefit management services to approximately 62 million members.’

44. Upon information and belief, Merck-Medco is the corporate predecessor of Medco Health Solutions Inc.

45. Since 2013, the County of Summit's PBM for its healthcare plan has been Express Scripts, Inc.

46. Defendants Express Scripts, Inc., Express Scripts Pharmacy, Inc., Express Scripts Holding Company, Medco Health Solutions, Inc., and Merck-Medco are collectively referred to herein as "ESI."

47. Defendant Optum, Inc., is a Delaware corporation, registered to do business in Ohio, with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth Group's pharmacy benefits, including OptumRx, Inc.

48. Defendant OptumRx, Inc., is a California corporation with its headquarters in Irvine, California. OptumRx, Inc. is registered to do business in Ohio. OptumRx, Inc. is a wholly owned subsidiary of Defendant UnitedHealth Group. UnitedHealth projected OptumRx to have \$112 billion in revenues in 2020.

49. Defendant UnitedHealth Group is a Delaware corporation with its principal place of business in Minnetonka, Minnesota. UnitedHealth Group serves approximately 115 million individuals throughout the United States. For 2016, UnitedHealth Group reported an operating income of \$12.9 billion.

50. Upon information and belief, Optum, Inc. is a subsidiary of UnitedHealth Group. OptumRx operates as a subsidiary of Optum, Inc. and as the PBM for UnitedHealth Group.

51. Defendants Optum Inc., OptumRx, and UnitedHealth Group are collectively referred to herein as "OptumRx."

BACKGROUND

What are PBMs?

52. Pharmacy Benefit Managers (PBMs), including ESI and OptumRx, are companies that administer prescription drug plans for entities that include insurers, self-insured employers, and state and federal government agencies (collectively, these entities are referred to as “plan sponsors”). PBMs review and pay claims; PBMs also review and decide “which medications are most effective for each therapeutic use.” In effect, a PBM’s plan can determine what medications will (or will not) be available, at what quantity and dosage, and how difficult it may be for a patient to receive that medication (e.g., by requiring pre-authorization).

53. In essence, because PBMs choose which drugs appear on their formularies, they wield significant influence over which drugs are disseminated throughout the County and how those drugs are paid for.

54. Defendant ESI performed all these tasks for large insurers in Ohio, including Medical Mutual of Ohio, thereby administering prescription drug plans for millions of Ohio residents. ESI performed these tasks for Summit County residents specifically both in connection with its role as PBM for the County of Summit health plan since 2013 and more generally for Summit County residents who received insurance from their employers or otherwise utilized ESI as a PBM.

55. Defendant OptumRx also performed these tasks for Summit County residents, in connection with its role as PBM for Summit County residents who received insurance from their employers, including but not limited to the State of Ohio, or otherwise utilized OptumRx as a PBM.

ESI's and OptumRx's Relationship with Manufacturers

56. ESI and OptumRx colluded with manufacturers by requiring and receiving financial incentives, such as rebates and administrative fees, in exchange for benefit plan design, formulary placement, and drug utilization management that result in more opioids entering the marketplace.

57. PBMs use utilization volume to drive discounts at the manufacturer level. Manufacturers typically offer rebates only for brand-name drugs, not generic products.

58. In addition to rebates, PBMs negotiate the payment of administrative fees, volume bonuses and other forms of consideration from manufacturers. PBMs' ability to negotiate these incentives from drug manufacturers derives from their control of the factors driving utilization, including formulary development and plan design.

59. These incentives include the payment of rebates by manufacturers to PBMs based on utilization, bonuses for moving product and hitting volume targets, and the payment of lucrative administrative fees to maximize PBM profits. Much of this activity is not transparent to anyone, including those who in good faith hire PBMs to manage their benefits.

60. On information and belief, and as described below, ESI and OptumRx engaged in all these practices in Ohio generally and in Summit County specifically.

PBMs and Formularies

61. PBMs, including ESI and OptumRx, require and receive incentives from manufacturers to keep certain drugs on and off formularies.

62. A drug formulary is a list of generic and brand name prescription drugs covered by health plans. Formularies are usually divided into three to five tiers that determine consumers' cost-share amounts, or the co-payment or co-insurance consumers must pay toward the cost of a

prescription. The lower tiers have lower cost-share amounts than the higher tiers. For example, a typical three-tier formulary may be designed as follows:

- Tier 1: contains generic drugs with the lowest cost-share amount for consumers
- Tier 2: contains preferred brand-name drugs with a cost-share amount that is higher than tier 1 but lower than Tier 3
- Tier 3: contains non-preferred brand-name drugs with the highest payment by consumers

63. Generally, PBMs require prescription drug manufacturers to pay higher rebates for preferred formulary placement (*i.e.*, tier 2 status instead of tier 3 status). This is because prescribers are more likely to write prescriptions and consumers to fill prescriptions for drugs with lower cost-share amounts.

64. PBMs' standard national formularies are adopted by health insurers and are the pathways by which opioids are dispensed around the country, including in Summit County.

65. The rebates PBMs negotiate are highly confidential and, for the most part, the exact terms of the agreements between PBMs and prescription drug manufacturers are unknown to others in the supply chain – creating a pricing black box.

66. Under a traditional PBM pricing model, PBMs retain a portion of the payments they receive from prescription drug manufacturers and return the remainder to their third-party health plan clients.

FACTUAL ALLEGATIONS

67. Express Scripts is one of the largest PBMs in the prescription drug industry.

68. Express Scripts acquired Medco Health Solutions Inc. in 2012 in a \$29.1 billion deal. Because of the merger, Express Scripts Holding Company (“ESHC”) was formed and became

the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers.

69. In 2015, the Pharmacy Benefit Management Institute found that ESI was the top ranking PBM nationwide with 26% of the industry market share.

70. Currently, ESI has a 38% market share, making it the largest PBM in the state of Ohio.

71. OptumRx was the third highest-ranking PBM in 2015 with 22% of the industry market share, according to the Pharmacy Benefit Management Institute.

72. ESI and OptumRx served as PBMs for employee insurance programs utilized by residents of Summit County.

73. ESI and OptumRx also dispense prescription opioids through their mail order pharmacies, serving patients nationally and throughout Ohio. Both ESI and OptumRx derive substantial revenue managing pharmacy benefits in Ohio, including within Summit County, through several means, including, but not limited to, providing services to companies in managing their employees' prescription benefit program. Upon information and belief, this is the primary method by which Express Scripts and OptumRx profit from prescription opioids - the management and control of opioid traffic and the subsequent reimbursement by private and government payors.

ESI and OptumRx Facilitated and Encouraged the Use of Opioids and Flooded the Market

74. ESI and OptumRx exert significant control over the prescribing, use, and distribution of opioids throughout Ohio. ESI and OptumRx determine what drugs are included on their formularies and, as such, what drugs will be reimbursed. In doing so, ESI and OptumRx control what drugs are dispensed by pharmacies and used by patients.

75. ESI's and OptumRx's formularies are heavily influenced by their financial agreements with drug manufacturers, which encourage the use of opioids through preferred formulary placement and ease the prescribing of opioids by lowering copayments (the amount paid by consumers when filling a prescription, hereinafter "copays") and failing to require prior authorization or quantity or dosage limits for opioid prescriptions.

76. Prior authorization, for example, requires advance approval from a health plan before a prescription drug is delivered to the patient to qualify for insurance coverage. Prior authorization requirements aim to ensure that a medication is necessary or that the patient filling the prescription meets the medical criteria for the use of the medication. These requirements impose an additional but important hurdle to opioid prescribing, which can reduce the illegitimate use and overuse of certain high-risk medications like opioids. [REDACTED]

[REDACTED]

77. ESI's relationship with Purdue demonstrates the inherent danger in these agreements with opioid manufacturers. ESI's preferential treatment of OxyContin facilitated the widespread use and over-use of the drug nationally and in Summit County, paving the way for the opioid epidemic. Motivated by its own profits, ESI acceded to Purdue's request not to impose prior authorization or other limits on the use of OxyContin.

78. [REDACTED]

[REDACTED]

79. [REDACTED]

[REDACTED]

80. Purdue undermined the policy for prior authorizations by offering enticing rebates to ESI on the condition that ESI eased availability of OxyContin and lowered copays. Thus, in

sum and substance, Purdue paid ESI in order to make OxyContin more available to patients – and ESI complied.

81. [REDACTED]

[REDACTED]

82. A former Purdue official responsible for ensuring favorable treatment for OxyContin explained, “We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug.”

83. [REDACTED]

[REDACTED]

[REDACTED] These early payments helped gain acceptance and use of OxyContin in the key early years after its launch and laid the foundation for the over-use, misuse, diversion and other harms that followed.

84. [REDACTED]

[REDACTED]

[REDACTED]

85. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

86. [REDACTED]

87. [REDACTED]

88. [REDACTED]

89. While ESI represented publicly that it approves drugs for its formulary through exhaustive clinical review based on their efficacy and appropriateness, as well as cost, it was actually ESI's rebates that drove its decisions. [REDACTED]

[REDACTED]

[REDACTED]

90. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

91. Upon information and belief, OptumRx had the same rebate arrangements with Purdue Pharma and other opioid manufacturers and, because of its financial interests, provided favorable formulary status to and failed to impose reasonable restrictions on opioids that were prescribed, dispensed, used, and diverted in Summit County.

92. Upon information and belief, ESI cooperated with Purdue not only in providing formulary access for OxyContin and other opioids, but in providing education to pharmacists to increase the use and acceptability of OxyContin [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

93. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

94. ESI, OptumRx, and other PBMs also provided cash discount cards that allowed patients to access opioids that were not covered by insurance.

95. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

96. Despite its knowledge of misuse and diversion of prescription opioids, OptumRx encouraged the use of highly addictive opioids through its formulary policies. For example, in one case, OptumRx suggested that a member using a Butrans patch consider switching to lower cost but more highly diverted alternatives, such as OxyContin or extended-release morphine.

97. Furthermore, UnitedHealth, including its subsidiaries, “places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a non-opioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first.”

98. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, OptumRx not only facilitated Purdue's opioid sales through its own formulary, but by helping to ensure that opioids would be widely prescribed, used, and covered by others.

I. ESI and OptumRx Had Access to Data Indicating Diversion, Misuse, and Abuse of Opioids

99. Both ESI and OptumRx had access to extraordinary data that would have allowed them to identify illegitimate and dangerous prescribing, dispensing, and use of opioids, as well as doctor-shopping, pharmacy-shopping, and other signs of misuse, abuse, and dangerous and illegitimate use, but failed to use that data to prevent diversion and other harm in Summit County.

100. ESI and OptumRx provided manufacturers with preferred formulary status without restrictions even though it knew that dangerous numbers of opioids were being utilized in Summit County and the nation and were causing an unprecedented crisis of addiction, overdose, and death.

101. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But ESI's own data, and the data it had access to from Purdue, demonstrated these problems as well.

102. ESI and OptumRx monitor their clients' and drug manufacturers' opioid utilization. They have extraordinary data across the opioid supply chain, including data showing: the volume, nature, dosage, and conditions for which health care providers are prescribing opioids to individual patients and on an aggregate basis; the volume of opioids obtained by individual patients and by geography (including signs of doctor- and pharmacy-shopping, early-refills, fatal and non-fatal overdoses, treatment for substance use disorders, co-prescribing with dangerous or commonly

abused drugs, such as benzodiazepines or the “Holy Trinity;”); the pharmacies at which opioids were dispensed and the volume of opioids dispensed by geographic area, among other data. ESI and OptumRx also track the number of opioids that move through their own mail order pharmacies.

103. Thus, ESI and OptumRx, like other PBMs, can see detailed information on individual prescribers and pharmacies, but can also aggregate that data across manufacturers, patients, pharmacies, and payors. Their visibility is both uniquely granular and comprehensive.

104. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

105. Upon information and belief, in its contracts with customers, Defendants represented that they would identify potential fraud and abuse, giving rise to an expectation that they were identifying and addressing instances of over-prescribing and diversion.

106. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

107. [REDACTED]

[REDACTED]

[REDACTED] Although the data could have been readily used to detect potential addiction and misuse, the Purdue-ESI partnership was focused more on ensuring the continued availability of its opioid products.

108. [REDACTED]

109. [REDACTED]

110. Both Purdue and ESI knew, based on the prescription data, that issues had emerged regarding the overprescribing of opioids. [REDACTED]

111. ESI had access to patient information as well. [REDACTED]

112. [REDACTED] ESI had a ringside seat to the earliest rounds of the opioid epidemic. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

113. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] While ESI was aware even at this early date of the signs of improper marketing and patient harm, it took no steps to protect the County or the nation from over-use of opioids.

114. [REDACTED]

[REDACTED]

[REDACTED]

115. *A Nation in Pain* found that 40% of opioid prescriptions filled by members with employer sponsored drug coverage between 2011 and 2012 were written by only 5% of prescribers.

116. Armed with a wealth of information and data, ESI and OptumRx knew or should have known of the dangerous prescribing patterns that demonstrated issues like diversion, misuse, abuse, doctor shopping, overdose, and outsized use in Summit County. Yet, upon information and belief, ESI and OptumRx took no steps to report or address outlier prescribers or pharmacies or to

otherwise rein in the facially suspicious volume of opioids being dispensed in Summit County or throughout the country.

117. Upon information and belief, ESI and OptumRx never disclosed information regarding the misuse, diversion, addiction, and overdose and did not warn Plaintiff or any of its other customers of such risks.

118. ESI and OptumRx knew or should have known from their own data that dangerous numbers of opioids were being dispensed Summit County and the surrounding communities—and yet they failed to take any of a number of steps they could have taken to stop it. For example, ESI and OptumRx could have implemented policies that provided easier access to non-addictive forms of pain relief, or that covered alternative, non-medication treatments for pain, or made addiction treatments more accessible.

119. Instead, ESI and OptumRx made it easier for doctors to prescribe and patients to obtain dangerous and highly addictive opioids, encouraging their use.

120. ESI and OptumRx failed to do anything about the opioid crisis that they knew existed because they were incentivized by payments from opioid manufacturers to ensure dangerous opioids were easier to access than safer alternatives.

121. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] By then, it was much too late for the millions of Ohio residents who were suffering from opioid addiction.

122. The belated steps that Defendants took demonstrate their ability to reduce the supply of opioids through appropriate formulary management steps that could, and should, have been taken far earlier.

123. [REDACTED]

124. While ESI publicly asserts that efforts to curb opioid abuse and misuse remain its highest priorities, its 2018 standard formulary still affords OxyContin, one of the most highly addictive opioids, preferred alternative status over other long-acting opioids.

125. Also far too late, OptumRx published a brochure in 2018, describing their “multi-dimensional approach to stop opioid abuse before it starts, while supporting individuals in their recovery.” The brochure described the opioid epidemic and touted that OptumRx’s Opioid Risk Management “is a comprehensive solution that uses advanced analytics and evidence-based clinical rules to help prevent opioid misuse, identify and intervene with at-risk and high-risk members, and support those with dependency through successful recovery. In turn, this reduces the devastating clinical, social and economic implications of opioid-related overdoses, hospitalizations and deaths – in a timely and targeted manner.”

126. ESI and OptumRx did not disclose to the County of Summit their financial incentives from Purdue or other manufactures or what they knew regarding bad doctors, diversion, and adverse consequences. ESI and OptumRx used their knowledge and scale for their own benefit, rather than their customers', causing injury to Summit County and the public.

II. As DEA Registrants, ESI and OptumRx Had To Comply With the Controlled Substances Act

127. ESI operates one of the largest mail order pharmacies in the United States, dispensing opioids to patients in Ohio as well as throughout the United States. OptumRx also operates a mail order pharmacy that dispenses opioids to patients throughout Ohio. As such, ESI and OptumRx are part of the closed system and are required to comply with the provisions of the Controlled Substances Act ("CSA") and Ohio laws.

128. ESI's and OptumRx's obligations as registrants included the responsibility to maintain effective controls against diversion of opioids. 21 C.F.R. § 1301.71(a). This includes an obligation to use the information available to them, such as the vast amounts of prescription and prescriber data they maintained or could access, to prevent the diversion of opioids. Upon information and belief, ESI and OptumRx failed to utilize this data to detect or guard against diversion, and otherwise failed to meet their CSA obligations.

129. ESI and OptumRx were also required to comply with Ohio's controlled substances law and pharmacy regulations. *See, e.g.*, O.A.C. §§ 4729:5-1-01, 4729:5-2-01 *et. seq.*, 4729:5-3-01 *et. seq.*, 4729:5-4-01, 4729:5-8-01 *et. seq.*, and O.R.C. §§ 4729.55 and 3719.07. This includes, but is not limited to, ensuring that adequate safeguards were in place to dispense opioids in a safe and effective manner, providing effective controls and procedures to deter and detect theft and diversion, and complying with federal controlled substances laws, such as the requirement to maintain effective controls against diversion. *See, e.g.*, O.R.C. § 4729.55 ("adequate safeguards

are assured that the applicant will carry on the business . . . in a manner that allows pharmacists . . . to practice pharmacy in a safe and effective manner”), O.A.C. § 4729:5-3-14 (requiring effective controls and procedures to deter and detect the theft and diversion of dangerous drugs), O.A.C. § 4729:5-4-01 (sanctions for violating any provision of the federal drug abuse control laws), and O.A.C. § 4729:5-8-03 (requiring compliance with all applicable laws, regulations, and standards set forth by the FDA and DEA). ESI and OptumRx failed to meet these obligations.

130. Instead, during the period for which ARCOS data is available (2006-2014), ESI shipped over 1 billion dosage units of opioids to patients in Summit County and across the nation, and OptumRx’s mail order pharmacy was responsible for more than 185 million dosage units.

131. In addition, ESI actively thwarted mechanisms that can prevent diversion. [REDACTED]

[REDACTED]

[REDACTED]

132. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

133. ESI’s oversight of its own mail order opioid dispensing was insufficient, permitting an untold number of opioids to be mailed even though those pills were likely to be diverted, and therefore should not have been shipped if ESI had complied with its obligations under the CSA.

134. In 2012, Express Scripts and Express Scripts Pharmacy Services, Inc. agreed to pay the U.S. Government \$2.75 million to settle a case against the companies. A DEA inspection revealed that from 2002 through 2006, prescription controlled substances were diverted into illicit channels at several ESI mail order facilities located in Pennsylvania. The diversion included thefts

by employees, inventory discrepancies, and failures to report to DEA losses that occurred during the mail order delivery process. Perhaps most disturbing, the DEA also found that ESI employees generated invalid DEA registration numbers where it lacked registration numbers from pharmacists, which should have been not only a red flag, but an absolute barrier to dispensing these drugs.

III. Defendants Created a Public Health Crisis in Summit County By Dramatically Increasing the Availability of Opioids

135. By facilitating and failing to address the overprescribing and overuse of opioids, by failing to address evidence of the overuse, abuse, and addiction to opioids, and failing to prevent diversion in its mail-order dispensing, Defendants contributed to the oversupply of opioids in Summit County and the resulting public nuisance. The huge amount of opioids that flooded into Summit County as a result of Defendants' wrongful and unreasonable conduct has devastated Summit County and its communities.

136. Ohio is among the states hardest hit by the opioid epidemic. "Opioid addiction, abuse, and overdose deaths have become the most pressing public health issue facing Ohio." Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and a half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids.

137. In Summit County, more people died from drug overdoses in 2015 and 2016 alone than the entire decade of 2000 to 2009. According to the CDC's Provisional data, there were an estimated 107,622 drug overdose deaths in the United States during 2021. That is nearly a 15% increase from the estimated deaths in 2020, which totaled 93,655

138. Ohio's Prescription Drug Abuse Task Force has found that individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar

high. Similarly, a study by the Ohio Substance Abuse Monitoring Network reported on the connection between oxycodone use and heroin addiction, finding that “young new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin,” often after OxyContin became too expensive or difficult to obtain.

139. This trend is so deadly that surges of fatal drug overdoses have outpaced the capacity of local morgues. Summit County has had to make use of the Ohio Department of Health’s refrigerated trailer known as a “mobile morgue unit” (originally intended for catastrophes leading to mass casualties), on five separate occasions.

140. Autopsy reports confirm that many of the deaths are related to oxycodone, hydrocodone, other prescription opioids, heroin, and fentanyl.

141. In addition to burn-out, the Summit County Medical Examiner’s Office has faced increased costs of overtime, laboratory, toxicology and other costs. Between 2012 and 2016, there was a 47% increase in autopsies, a 436% increase in toxicology lab costs to identify new drugs, mostly synthetic opioids that have swept up individuals already addicted to opioids, and a 100% increase in the costs to transport the bodies.

142. As communities have worked to save lives, the opioid epidemic has continued to outpace their efforts. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. Addiction treatment centers in Summit County report that the majority of their patients who abuse heroin migrated from prescription opioids, particularly once doctors cut off their prescriptions.

143. The costs of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. Between 2012 and 2016, the County

of Summit estimates that it spent roughly \$66 million on costs tied to the opioid crisis. The County continues to spend millions of dollars “simply trying to keep up with the epidemic.”

CLAIM FOR RELIEF

Common Law Absolute Public Nuisance

144. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

145. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiff.

146. A public nuisance is an unreasonable interference with a right common to the general public.

147. Defendants have created and maintained a public nuisance by colluding with manufacturers to make opioids more available, by ignoring evidence of addiction and misuse found in their own claims data, and by failing to maintain effective controls against diversion, leading to the oversupply of opioids in Summit County. Defendants’ actions unreasonably interfere with the public health, welfare, and safety in Summit County, and the County and its residents have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person or property.

148. The public nuisance is an *absolute* public nuisance because the Defendants’ nuisance-creating conduct was intentional and unreasonable and/or violated statutes, such as 21 C.F.R. 1301.71(a), O.A.C. §§ 4729:5-1-01, 4729:5-2-01 *et. seq.*, 4729:5-3-01 *et. seq.*, 4729:5-4-01, 4729:5-8-01 *et. seq.*, and O.R.C. §§ 4729.55, which established specific legal requirements for the protection of others.

149. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of facilitating and encouraging the use of dangerously addictive opioids by colluding with manufacturers to place opioid drugs on formularies with preferred status, declining to impose limits on their approval for use in exchange for payments and fees from manufacturers, assisting in promoting but failing to disclose the real risks and appropriate limits on the use of opioids, and failing to use the wealth of data available to them to identify and address signs of over-prescribing, illegitimate and dangerous use of opioids, misuse, abuse, and diversion. Their conduct caused prescriptions and sales of opioids to skyrocket and failed to limit their use even as evidence of the epidemic mounted, including in Summit County, flooding the County with opioids and facilitating and encouraging the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiff and the residents of Plaintiff's Community.

150. Defendants knew, or should have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Summit County and its residents.

151. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Summit County and its residents. *See* Restatement (Second) of Torts § 821B.

152. The interference is unreasonable because Defendants' nuisance-creating conduct:

- a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

- b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or
- c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

153. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

- a. The creation and fostering of an illegal, secondary market for prescription opioids;
- b. Easy access to prescription opioids by children and teenagers;
- c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;
- d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
- e. Employers have lost the value of productive and healthy employees; and
- f. Increased costs and expenses for Plaintiff relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

154. Defendants intentionally and unreasonably and/or unlawfully pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Summit County, a higher level of fear, discomfort and inconvenience to the residents of Summit County, and direct costs to Summit County and its residents.

155. Defendants are liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of the Defendants were a substantial factor in producing the public nuisance and harm to Plaintiff.

156. In its role as a dispenser of opioids in Ohio and Summit County, Defendants violated federal law, including, but not limited to 21 C.F.R. § 1301.71(a), and Ohio law, including, but not limited to O.A.C. §§ 4729:5-1-01, 4729:5-2-01 *et. seq.*, 4729:5-3-01 *et. seq.*, 4729:5-4-01, 4729:5-8-01 *et. seq.*, and O.R.C. §§ 4729.55.

157. Defendants' unlawful and unreasonable nuisance-creating conduct includes violating federal and Ohio statutes and regulations, including the controlled substances laws, by dispensing opioids without maintaining effective controls against diversion, including but not limited to failing to utilize their own data and the data available to them to detect or guard against diversion.

158. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

- a. Facilitating the increased use of opioids by giving opioids preferred formulary status in exchange for payments from opioid manufacturers;
- b. Failing to impose limits on approval for the use of opioids in exchange for payments from opioid manufacturers;
- c. Increasing the number of opioid prescriptions;
- d. Ignoring evidence of addiction and abuse found in its own claims data; and
- e. Failing to maintain effective controls against the diversion of opioids.

159. At all times relevant to this Complaint, Defendants knew that increasing the availability of opioids would increase the number of opioids that would be abused, misused, and

diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

160. At all times relevant to this Complaint, Defendants knew that opioids were dangerous because these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

161. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful and unreasonable conduct of pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiff – exactly as would be expected when medical grade heroin in the form of prescription opioids flood the community and are diverted into an illegal, secondary market.

162. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiff described herein.

163. Because of Defendants' actions to make opioids more available in the marketplace and Defendants' special position within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

164. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Summit County and the harm inflicted outweighs any offsetting benefit.

165. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

166. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

167. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer stigma damage, property damage, and damage to its proprietary interests.

168. The nuisance created by Defendants' conduct is abatable.

169. Defendants' misconduct alleged in this case is ongoing and persistent, as is the nuisance to which they substantially contributed.

170. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

171. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

172. Plaintiff seeks to abate the nuisance created by Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

173. Plaintiff has suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Ohio citizens at large. These are harms that can only be suffered by Plaintiff.

174. Plaintiff is asserting its own rights and interests and Plaintiff's claims are not based upon or derivative of the rights of others.

175. The tortious conduct of the Defendants was a substantial factor in creating the absolute public nuisance.

176. The tortious conduct of the Defendants was a substantial factor in producing harm to Plaintiff.

177. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of the Defendants.

178. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

179. Plaintiff asserts this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this claim, Plaintiff does not seek damages for death, physical injury to person, emotional distress, or physical damages to property, as defined under the Ohio Product Liability Act.

180. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement, restitution, disgorgement of profits, attorneys' fees and costs, pre and post-judgment interest, and such other relief as this Court deems appropriate.

PRAYER FOR RELIEF

181. Plaintiff respectfully request that this Court enter an order of judgment granting all relief requested in this complaint, and/or allowed at law or in equity, including:

- a. abatement of the nuisance;

- b. equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;
- c. disgorgement of unjust profits
- d. costs and expenses of suit;
- e. pre- and post-judgment interest; and
- f. such other and further relief as this Court deems appropriate.

Dated: January 4, 2023

Respectfully submitted,

/s/ Linda Singer

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